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10/553,288

11/13/2006

Anna Medvedev

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06/28/2010

THE NATH LAW GROUP

112 South West Street

Alexandria, VA 22314

EXAMINER

MELLER, MICHAEL V

ART UNIT

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1655

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

| | | | |
|------------------------------|--------------------------------------|--|--|
| Office Action Summary | Application No. 10/553,288 | Applicant(s) MEDVEDEV ET AL. | |
| | Examiner Michael V. Meller | Art Unit 1655 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 15 June 2010.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 91-112 and 114-122 is/are pending in the application.
- 4a) Of the above claim(s) 103, 104 and 107-112 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 91-102, 105, 106, 114-122 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Election/Restrictions

1. Applicant's election **without traverse of Group I, claims 91-102, 105-107, 113, all of the ACPE components of claim 91, Penicillium digitatum, P. acnes, acne, lotion and not used as an antioxidant** in the reply filed on 2/2/2009 is acknowledged.

The requirement for election to P. acnes and acne is dropped.

Thus, claims 103, 104, 107-112 are withdrawn from further consideration as being drawn to non-elected inventions.

Claim Rejections - 35 USC § 102

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

3. Claims 91-101, 105, 106, 114-120, 122 are rejected under 35 U.S.C. 102(b) as being anticipated by IL 120929 (hereafter IL-supplied by applicants which includes an abstract and a translation).

IL teaches that citrus peels are exposed to *Penicillium digitatum*, see the entire reference, especially the abstract, pages 1, 4, 5, the claims. The use of the composition to be adapted for treatment of skin conditions associated (and not) with a bacterial or fungal infection is inherent to the composition since it is in powder form which can be applied to skin, see page 4 of IL. Further the type of bacterial or fungal infection to be treated is inherent since the claims are to a product and not to the method of using the product. The product as disclosed in IL will inherently treat the bacterial infections claimed. Further the skin conditions claimed do not carry any patentable weight since this claim is to a product and not to the method of using the product. Thus, the composition can potentially treat all of the claims skin conditions.

It is inherent that oligosaccharides, short peptides, flavanoid glycosides, fatty acids and triglycerides are present in the amounts claimed in the composition of IL since the composition of IL was made the same way as applicant's was, applicants even admit this on page 2 of the instant specification.

Art Unit: 1655

Applicant argues that IL does not teach the newly claimed step of filtering the extract liquid. While this is noted, it does not matter since this is a product claim and the claims still use “comprising” in the claims, thus any other substances not in the resulting extract after filtration are still in the claimed extract and the extract of IL.

The intended use of the extract to preserve foods, beverages and the like is inherent to the composition of IL since it is the same composition.

Applicant argues in their response filed 6/15/2010 that allegedly the ‘929 patent (IL) does not describe a composition comprising an activated citrus peel extract (ACPE) as prepared according to the present invention. In fact, applicant argues that the ‘929 patent does not describe the procedure for making the ACPE of the present invention, but the claims are limited to a product by process not the process.

Since the applicants admit on the record that the extract claimed is made by the same process as detailed in the instant specification on page 2, then the claimed amounts of each component (oligosaccharides, short peptides, flavanoid glycosides, fatty acids and triglycerides) are inherently taught by IL since applicants have admitted on page 2 that, “the ACPE used in the compositions of the present invention is characterized as being prepared by a method which involves contacting of the citrus

Art Unit: 1655

peels with at least one pathogen prior to extraction, said method hereon referred to as the 'activation method'. The extract obtained from such a method is hereon referred to as the 'activated extract' or as ACPE. The activation method may for example be the method disclosed in Israel Patent No. 120929 or the method of the present invention as disclosed hereinafter". Thus, exactly the same extract as claimed is taught by IL as admitted by applicant's themselves on page 2 of the instant specification.

Applicant next argues that the ACPE extract as claimed was allegedly 4 times as active against *Cladosporium* as was the extract of IL and twice as active against *E. coli* compared to the extract disclosed in IL. Next applicant refers to page 20 of the instant specification to show alleged unexpected results but such results are not persuasive. Simply because the instantly claimed extract was 4 times as active against *Cladosporium* as compared to the extract of IL and twice as active against *E. coli* as compared to the extract of IL is not unexpected results. These are only two specific microorganisms and such evidence is very limited in its disclosure. Further, it is not clear what is meant by "active against" ? What does this really mean or conclude about the instantly claimed extract versus the extract of IL. Thus, the results are inconclusive. Further, this is a 35 USC 102 rejection and unexpected results do not apply in 35 USC 102 rejections, thus this argument is moot.

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

5. Claims 91-102, 105, 106, 114-122 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over IL 120929 (hereafter IL-supplied by applicants which includes an abstract and a translation).

IL teaches that citrus peels are exposed to *Penicillium digitatum*, see the entire reference, especially the abstract, pages 1, 4, 5, the claims. IL teaches that citrus peels are exposed to *Penicillium digitatum*, see the entire reference, especially the abstract, pages 1, 4, 5, the claims. The use of the composition to be adapted for treatment of skin conditions associated (and not) with a bacterial or fungal infection is inherent to the composition since it is in powder form which can be

Art Unit: 1655

applied to skin, see page 4 of IL. Further the type of bacterial or fungal infection to be treated is inherent since the claims are to a product and not to the method of using the product. The product as disclosed in IL will inherently treat the bacterial infections claimed. Further the skin conditions claimed do not carry any patentable weight since this claim is to a product and not to the method of using the product. Thus, the composition can potentially treat all of the claims skin conditions.

It is inherent that oligosaccharides, short peptides, flavanoid glycosides, fatty acids and triglycerides are present in the amounts claimed in the composition of IL since the composition of IL was made the same way as applicant's was, applicants even admit this on page 2 of the instant specification.

IL teaches a composition comprising an extract of citrus peels that are exposed to *Penicillium digitatum* which appears to be identical to (and thus anticipate) the presently claimed composition since both were prepared using the method as admitted by applicants on page 18, example 1 of the instant specification. Consequently, the instantly claimed extract composition appears to be anticipated by the cited reference.

In the alternative, even if the claimed extract composition is not identical to the referenced extract composition with regard to some unidentified characteristics, the differences between that which is disclosed and that which is claimed are considered to

Art Unit: 1655

be so slight that the referenced extract composition is likely to inherently possess the same characteristics of the claimed extract composition. Thus, the claimed extract composition would have been obvious to those of ordinary skill in the art within the meaning of USC 103. Further, if not anticipated, the result-effective adjustment of particular conventional working conditions (e.g., conventional temperatures, heating, pH, etc.) is deemed merely a matter of judicious selection and routine optimization which is well within the purview of the ordinary artisan.

Accordingly, the claimed invention as a whole was at least prima facie obvious, if not anticipated by the reference, especially in the absence of sufficient, clear, and convincing evidence to the contrary.

Please note that the Patent and Trademark Office is not equipped to conduct experimentation in order to determine whether the claimed extract differs and, if so, to what extent, from extract disclosed by the cited reference. Therefore, with the showing of the reference, the burden of establishing non-obviousness by objective evidence is shifted to the Applicants.

Please also note that “the patentability of a product does not depend upon its method of production. If the product in [a] product-by-process claim is the same as or obvious from a product of the prior art, [then] the claim is unpatentable even though the prior [art] product was made by a different process.” *In re Thorpe*, 227 USPQ 964, 966 (Fed. Cir. 1985). Once the examiner provides a rationale tending to show that the claimed product appears to be the same or similar to that of the prior art, although

Art Unit: 1655

produced by a different process, the burden shifts to applicant to come forward with evidence establishing an unobvious difference between the claimed product and the prior art product. In re Marosi, 218 USPQ 289, 292 (Fed. Cir. 1983).

Applicant argues that IL does not teach the newly claimed step of filtering the extract liquid. While this is noted, it does not matter since this is a product claim and the claims still use "comprising" in the claims, thus any other substances not in the resulting extract after filtration are still in the claimed extract and the extract of IL.

The intended use of the extract to preserve foods, beverages and the like is inherent to the composition of IL since it is the same composition.

Next applicant refers to page 20 of the instant specification to show alleged unexpected results but such results are not persuasive. Simply because the instantly claimed extract was 4 times as active against *Cladosporium* as compared to the extract of IL and twice as active against *E. coli* as compared to the extract of IL is not unexpected results. These are only two specific microorganisms and such evidence is very limited in its disclosure. Further, it is not clear what is meant by "active against" ? What does this really mean or conclude about the instantly claimed extract versus the extract of IL. Thus, the results are inconclusive.

Applicant argues in their response filed 6/15/2010 that allegedly the '929 patent (IL) does not describe a composition comprising an activated citrus peel extract (ACPE) as prepared according to the present invention. In fact, applicant argues that the '929 patent does not describe the procedure for making the ACPE of the present invention, but the claims are limited to a product by process not the process.

Since the applicants admit on the record that the extract claimed is made by the same process as detailed in the instant specification on page 2, then the claimed amounts of each component (oligosaccharides, short peptides, flavanoid glycosides, fatty acids and triglycerides) are inherently taught by IL since applicants have admitted on page 2 that, "the ACPE used in the compositions of the present invention is characterized as being prepared by a method which involves contacting of the citrus peels with at least one pathogen prior to extraction, said method hereon referred to as the 'activation method'. The extract obtained from such a method is hereon referred to as the 'activated extract' or as ACPE. The activation method may for example be the method disclosed in Israel Patent No. 120929 or the method of the present invention as disclosed hereinafter". Thus, exactly the same extract as claimed is taught by IL as admitted by applicant's themselves on page 2 of the instant specification.

Applicant next argues that the ACPE extract as claimed was allegedly 4 times as active against *Cladosporium* as was the extract of IL and twice as active against *E. coli* compared to the extract disclosed in IL. Next applicant refers to page 20 of the instant specification to show alleged unexpected results but such results are not persuasive. Simply because the instantly claimed extract was 4 times as active against *Cladosporium* as compared to the extract of IL and twice as active against *E. coli* as compared to the extract of IL is not unexpected results. These are only two specific microorganisms and such evidence is very limited in its disclosure. Further, it is not clear what is meant by "active against" ? What does this really mean or conclude about the instantly claimed extract versus the extract of IL. Thus, the results are inconclusive.

Further, it is noted that IL does teach an extracted liquid which is yielded as noted on page 4 of IL. This could be a lotion. In the event that it is felt that this does not read on a lotion (which this examiner highly doubts) then it is submitted that it would have been well within the purview of the ordinary artisan to make a lotion from the "liquid" of IL since IL intends the composition to be used for medicinal purposes and a well known liquids used for medicinal purposes are clearly known in the art to be a lotion. Lotions provide the vehicles to deliver all kinds of drugs to the body. Further, the definition of a lotion is very broad which clearly reads on a liquid, a liquid can be a type of lotion.

6. Claims 91-102, 105, 106, 114-122 are rejected under 35 U.S.C. 103(a) as being unpatentable over IL 120929 (hereafter IL-supplied by applicants which includes an abstract and a translation).

IL teaches that citrus peels are exposed to *Penicillium digitatum*, see the entire reference, especially the abstract, pages 1, 4, 5, the claims. IL teaches that citrus peels are exposed to *Penicillium digitatum*, see the entire reference, especially the abstract, pages 1, 4, 5, the claims. The use of the composition to be adapted for treatment of skin conditions associated (and not) with a bacterial or fungal infection is inherent to the composition since it is in powder form which can be applied to skin, see page 4 of IL. Further the type of bacterial or fungal infection to be treated is inherent since the claims are to a product and not to the method of using the product. The product as disclosed in IL will inherently treat the bacterial infections claimed. Further the skin conditions claimed do not carry any patentable weight since this claim is to a product and not to the method of using the product. Thus, the composition can potentially treat all of the claims skin conditions.

Art Unit: 1655

It is inherent that oligosaccharides, short peptides, flavanoid glycosides, fatty acids and triglycerides are present at the amounts claimed in the composition of IL since the composition of IL was made the same way as applicant's was, applicants even admit this on page 2 of the instant specification.

Since the applicants admit on the record that the extract claimed is made by the same process as detailed in the instant specification in example 1, then it clearly would have been obvious to make and yield the claimed extract including the amounts of each component (oligosaccharides, short peptides, flavanoid glycosides, fatty acids and triglycerides) since such extractions procedures were well within the purview of the ordinary artisan in an effort to optimize the desired results.

MPEP 2144.05 Obviousness of Ranges

II. OPTIMIZATION OF RANGES

A. Optimization Within Prior Art Conditions or Through Routine Experimentation

Generally, differences in concentration or temperature will not support the patentability of subject matter encompassed by the prior art unless there is evidence indicating such concentration or temperature is critical. "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." In re Aller, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955) (Claimed process which was performed at a temperature between 40°C and 80°C and an acid concentration between 25% and 70% was held to be prima facie obvious over a reference process which differed from the claims only in that the reference process was performed at a temperature of 100°C and an acid concentration

Art Unit: 1655

of 10%.); see also Peterson, 315 F.3d at 1330, 65 USPQ2d at 1382 ("The normal desire of scientists or artisans to improve upon what is already generally known provides the motivation to determine where in a disclosed set of percentage ranges is the optimum combination of percentages."); In re Hoeschele, 406 F.2d 1403, 160 USPQ 809 (CCPA 1969) (Claimed elastomeric polyurethanes which fell within the broad scope of the references were held to be unpatentable thereover because, among other reasons, there was no evidence of the criticality of the claimed ranges of molecular weight or molar proportions.). For more recent cases applying this principle, see Merck & Co. Inc. v. Biocraft Laboratories Inc., 874 F.2d 804, 10 USPQ2d 1843 (Fed. Cir.), cert. denied, 493 U.S. 975 (1989); In re Kulling, 897 F.2d 1147, 14 USPQ2d 1056 (Fed. Cir. 1990); and In re Geisler, 116 F.3d 1465, 43 USPQ2d 1362 (Fed. Cir. 1997).

Thus, to make and yield the claimed extracts was well within the purview of the ordinary artisan through routine experimentation since as stated above, "the normal desire of scientists or artisans to improve upon what is already generally known provides the motivation to determine where in a disclosed set of percentage ranges is the optimum combination of percentages.", thus in this case, to use different temperatures, pH conditions, etc. was well within the purview of the ordinary artisan in an effort to optimize the desired results.

Further, it is noted that IL does teach an extracted liquid which is yielded as noted on page 4 of IL. This could be a lotion. In the event that it is felt that this does not read on a lotion (which this examiner highly doubts) then it is submitted that it would have been well within the purview of the ordinary artisan to make a lotion from the "liquid" of IL since IL intends the composition to be used for medicinal purposes and a well known liquid used for medicinal purposes is clearly known in the art to be a lotion.

Art Unit: 1655

Lotions provide the vehicles to deliver all kinds of drugs to the body. Further, the definition of a lotion is very broad which clearly reads on a liquid, a liquid can be a type of lotion.

Applicant argues that IL does not teach the newly claimed step of filtering the extract liquid. While this is noted, it does not matter since this is a product claim and the claims still use "comprising" in the claims, thus any other substances not in the resulting extract after filtration are still in the claimed extract and the extract of IL.

The intended use of the extract to preserve foods, beverages and the like is inherent to the composition of IL since it is the same composition.

Next applicant refers to page 20 of the instant specification to show alleged unexpected results but such results are not persuasive. Simply because the instantly claimed extract was 4 times as active against *Cladosporium* as compared to the extract of IL and twice as active against *E. coli* as compared to the extract of IL is not unexpected results. These are only two specific microorganisms and such evidence is very limited in its disclosure. Further, it is not clear what is meant by "active against" ? What does this really mean or conclude about the instantly claimed extract versus the extract of IL. Thus, the results are inconclusive.

Next applicant argues that the “age” of the microorganisms should have bearing on the patentability of the claims. Fact is, microorganisms such as bacteria and fungi are immortal, that is they never die unless they are expressly killed by heat for instance. Thus, to say that the microorganisms are 16-24 hours or 8 day to 14 day old microorganisms is meaningless since bacteria and fungi exist well beyond such amounts of time. If they are killed then clearly they cannot be used in the claimed process.

Further, the same extract will be yielded as claimed in the process of IL since the same microorganisms are used, whether or not they are the same age does not change the fact that the extract yielded by IL is the same as instantly claimed.

Applicant argues in their response filed 6/15/2010 that allegedly the ‘929 patent (IL) does not describe a composition comprising an activated citrus peel extract (ACPE) as prepared according to the present invention. In fact, applicant argues that the ‘929 patent does not describe the procedure for making the ACPE of the present invention, but the claims are limited to a product by process not the process.

Since the applicants admit on the record that the extract claimed is made by the same process as detailed in the instant specification on page 2, then the claimed

Art Unit: 1655

amounts of each component (oligosaccharides, short peptides, flavanoid glycosides, fatty acids and triglycerides) are inherently taught by IL since applicants have admitted on page 2 that, "the ACPE used in the compositions of the present invention is characterized as being prepared by a method which involves contacting of the citrus peels with at least one pathogen prior to extraction, said method hereon referred to as the 'activation method'. The extract obtained from such a method is hereon referred to as the 'activated extract' or as ACPE. The activation method may for example be the method disclosed in Israel Patent No. 120929 or the method of the present invention as disclosed hereinafter". Thus, exactly the same extract as claimed is taught by IL as admitted by applicant's themselves on page 2 of the instant specification.

Applicant next argues that the ACPE extract as claimed was allegedly 4 times as active against *Cladosporium* as was the extract of IL and twice as active against *E. coli* compared to the extract disclosed in IL. Next applicant refers to page 20 of the instant specification to show alleged unexpected results but such results are not persuasive. Simply because the instantly claimed extract was 4 times as active against *Cladosporium* as compared to the extract of IL and twice as active against *E. coli* as compared to the extract of IL is not unexpected results. These are only two specific microorganisms and such evidence is very limited in its disclosure. Further, it is not clear what is meant by "active against" ? What does this really mean or conclude about the instantly claimed extract versus the extract of IL. Thus, the results are inconclusive.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael V. Meller whose telephone number is 571-272-0967. The examiner can normally be reached on Monday thru Thursday: 9:30am-6:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Terry McKelvey can be reached on 571-272-0775. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Michael V. Meller
Primary Examiner
Art Unit 1655

Application/Control Number: 10/553,288
Art Unit: 1655

Page 19

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Primary Examiner, Art Unit 1655